fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug.

REMARKS

As per the above referenced Advisory Action, the Examiner has withdrawn the objections to the drawings, the specification, and claim 21. In addition, the rejection of Claim 8 under 35 USC 112, second paragraph has likewise been withdrawn.

Thus, the rejections of claims 1, 15 and 16 under 35 USC 102(b) and 2, 6-9, 17-18, 20 and 21 under 35 USC 103(a) remain. Theses rejections are respectfully traversed.

Claims 1, 5 and 16 have been rejected under 35 USC 102(b) as being anticipated by Michel et al. ("Michel"). Applicant respectfully traverses this rejection. The Examiner states that Michel teaches "a valve . . . wherein fluid flow is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds [sic] a pressure on the inlet end caused by the dead weight of the fluid drug." Applicant respectfully requests the Examiner to point out specifically within the reference where such a statement has support. Applicant respectfully asserts that Michel teaches nothing of the sort. As such, the reference cannot anticipate the claim.

Rather, the Examiner appears to be relying on the summary conclusion that addressing the issues related to the dead weigh of the fluid are "a phenomenon common to all syringe type devices with a piston." If the Examiner maintains such a conclusory statement, he is respectfully requested to provide a reference that teaches the concept. Michel does not address the issue at all, let alone anticipate the presently claimed invention. Michel does not actually teach a specific valve structure whatsoever, but merely indicates that a valve could be utilized. However, the purpose of such valve, as indicated at Col 6, lines 1-6 and Col 5, lines 1-6 is to provide a bypass passageway that can be selectively externally and manually opened and closed to allow the introduction of additional fluids. The graphs of FIGS. 2a-2e indicate the various delivery options. That of FIG. 2D indicates a continuous administration in combination with the sporadic introduction of a bolus 44. That is what the valve would be provided for. It would be manually opened or closed and has no relation to the fluid pressure contained within container 3. The only reference to the contrary is the Examiner's conclusory statement. As Michel fails to teach each and every element of at least claim 1, Applicant respectfully request that the Examiner withdraw the rejections.

In the Advisory Action, the Examiner has made various comments with reference to the Michel et al. reference. In summary, the Examiner appears to be saying that even though no valve is present (as discussed by the Examiner), a restricting portion is present which affects pressure. Thus, on some generic level Michel et al. teaches a device that is effectively "valved" and since the present claims deal with a valve, the reference anticipates them. Applicant respectfully traverses the Examiner's conclusions and their summary application to the present claims.

With all due deference to the Examiner's discussion of capillary action, fluid dynamics, fluid resistance, fluid flow rates, and his "construing" of these topics to indicate a "second valve," the issue is not nearly that complicated. It is simply whether the Examiner may construe a valve when there is no such valve actually taught by Michel. However, whether we address the valve imagined by the Examiner or the valve actually taught by the reference, the result is the same. Neither address or teaches the structure presently claimed. According to claim 1 the valve of the present invention has an inlet end adjacent the outlet and an outlet end adjacent the injection needle, wherein the valve permits flow of the fluid drug through the valve from the outlet to the injection needle when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug. Nowhere in Michel et al. is this concept of the dead weight of the fluid addressed nor would it be, based on an understanding of the Michel et al. invention. The valve structures actually discussed by Michel et al. or "construed" into existence by the Examiner do not meet this limitation; thus, the claims cannot be anticipated.

Claims 2 and 6-9 were rejected under 35 USC 103(b) as being unpatentable over Michel in view of Paradis. The Examiner asserts that Michel provides all of the limitations of the claims but fails to teach the specific valve structures claimed. Applicant respectfully traverses these rejections. As explained above, Michel fails to teach opening a valve when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug. Rather, Michel provides a valve that is manually opened and closed to allow the introduction of additional fluids and fails to address the issue of the dead weight of the fluid. Michel provides no teaching or motivation to add a valve to address such an issue and the only suggestion provided by the Examiner is Applicant's own claim language – thus clearly falling within the scope of impermissible hindsight.

Pardis fails to provide for the deficiencies noted above. Furthermore, the valve structure taught by Pardis is incompatible with the objective of Michel in that selective additional fluid flow cannot be controlled with the check valve taught by Pardis. That is, fluid flow in one direction is always allowed with the Pardis device. In addition, Pardis is only concerned with the prevention of back-flow – an a feature erroneously read into the claims and focused on by the Examiner. Thus, Michel and Pardis alone or in combination fail to teach the presently claimed invention and the Examiner is respectfully requested to withdraw the rejection.

Even if, as suggested by the Examiner in the Advisory Action, the Examiner's "construed" or imagined valve is augmented by the teachings of Pardis, the present claim limitations are still not met. It is simply incorrect for the Examiner to continually ignore the positively claimed elements addressing the issue of the dead weight of the fluid. Simply providing a valve structure of some sort – i.e., the back-flow preventing valve of Pardis, does not address such a limitation. That is, the Examiner appears to be under that impression that any valve provided in a reference teaching a drug delivery device meets the elements of the claims. If such is the case, the Examiner is not considering all of the elements of the claims, and this is entirely inappropriate. The Examiner is again specifically requested to provide an explicit teaching showing that a valve has been configured such that it will not open until a pressure exceeding the dead weight of the fluid has been provided. None of the references provided address the issue, let along teach the claims presently at issue.

Claims 17-18, 20 and 21 were rejected under 35 USC 103(a) as being unpatentable over Boettger in view of Pardis. Applicant respectfully traverses these rejections. Again the Examiner seems to have confused a valve whose only purpose is the prevention of back-flow with the presently claimed valve that permits flow of the fluid drug through the valve from the outlet to the injection needle when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug. Furthermore, the Examiner again states that this reference also teaches that the "flow of fluid is permitted . . . when pressure is exerted . . . exceeds [sic] a pressure . . . caused by the dead weight of the fluid drug." Boettger teaches no such concept. Rather, Boettger teaches a valve that is opened upon assembly of the components and prevents back-flow. Col. 5, lines 50-62 and Col. 6, lines 15-19. Boettger does not address or provide a mechanism to address the issue of the dead weight of the fluid. If the Examiner continues

to maintain his position, Applicant respectfully request that the Examiner point to specific language within the reference that supports that assertion.

The Examiner does not specify what he believes is lacking from Boettger and what Paradis is relied on for. Thus, Applicant asserts that Boettger is deficient, as explained above and Paradis does not provide what Boettger lacks. The Examiner does state that "it appears that claim 21 would allow for fluid to pass back into the container as addressed in the objections." This statement is factually incorrect, but also completely irrelevant to the claimed subject matter. Applicant once again points out that the force exerted by the dead weight of the fluid is in a direction opposite to that of any potential back-flow. Furthermore, the device of claim 21 is also quite capable of preventing backflow, but such a requirement is not part of the claim.

Applicant respectfully asserts that all of the pending claims patentably define over the prior art. As such, the Examiner is respectfully requested to withdraw the rejections and pass this case to issue. Further, as the previously identified generic claims are in condition for allowance, the Examiner is also respectfully requested to allow the claims to species withdrawn from consideration.

Respectfully submitted,

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MARKED-UP VERSION SHOWING CHANGES

17. (Once Amended) A device for the metered administration of a fluid drug, comprising:

(a) a housing positioned between an outlet of an ampoule containing a fluid drug and an injection needle; and

(b) a valve positioned in the housing in a flow cross section of the fluid drug, the valve having an inlet end adjacent the ampoule and an outlet end adjacent the injection needle, wherein the housing pretensions the valve at a contact surface thereof against an aperture of a feed line through the housing to the valve, the contact surface sealingly closing the aperture [at one pressure.] wherein the valve permits flow of the fluid drug through the valve from the inlet end to the outlet end when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug.